

FLORA 1200

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Kleiman *et al.* Atty Docket No.: FLORA.1100
Serial No.: 09/899,432 Group Art Unit: 1617
Filed: 07/06/2001 Examiner: Shobha Kantamneni
TITLE: **ANTIVIRAL COMPOSITION AND TREATMENT METHOD**

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to "Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on:

Date: _____ By: _____
Printed Name: _____

**AFFIDAVIT
PURSUANT TO 37 C.F.R. §1.132**

Assistant Commissioner of Patents
Alexandria, VA 22313-1450

Dear Assistant Commissioner:

STATE OF ARIZONA)
 ;
COUNTY OF MARICOPA)

I, David Ashley, being duly sworn, depose and say as follows:

I received a Bachelors of Science in Chemistry from Arizona State University in May of 1987. I have been employed by International Flora Technologies, Inc., (Technical Department) since 2003 where I serve as a chemist. Previously, I was employed at Safety-Kleen Systems, Inc., where I served as Compliance Manager from 2002-2003. I have also worked in various technical and managerial capacities at Onyx Environmental Services (Salesco Systems USA, Inc.), ADFlex Solutions Inc., and Revlon Consumer Products Corporation. I have over fourteen years of experience in analytical chemistry, environmental, health, and safety management. I am a Certified Hazardous Material Manager, and a member of the American Chemical Society.

I have undertaken an extensive review of United States Patent Application Serial No. 09/899,432. The invention referenced therein is directed to methods for treating virus-induced and inflammatory diseases utilizing topical compositions that include monounsaturated long chain alcohols in combination with long chain fatty acid salts and fatty acid esters. This combination results in a dramatic increase in antiviral activity, as shown in Tables 2 and 3 of the application as filed. Specifically, Tables 2 and 3 show the relative plaque growth 48 hours after the introduction of this combination (in various concentrations) into wells containing a standard HSV-1 control (strain 6143) (see Table 2) and the acyclovir resistant HSV-1 (strain 15671) (see Table 3). What is surprising is that this combination was effective against the treatment resistant strain, and that it required lower IC_{50} concentrations than the non-resistant strain. Moreover, the combination demonstrated no cytotoxicity up to, and including, concentrations of 250 mg/ml, the highest concentration tested.

Further, the cellular proliferation of cells exposed to the Herpes Simplex Type 1 Virus treated with the present invention showed up to a 238% increase over untreated (or control) cells in a microculture tetrazolium assay, as shown in Table 1 of the application as filed. Thus, the combination of monounsaturated long chain alcohols with long chain fatty acid salts and fatty acid esters creates unexpected cytotoxicity profiles.

The cytotoxicity profiles of long chain alcohols, salts of fatty acids, and mixed fatty acid esters alone is different from that of the combination. While it is known that long chain alcohols and fatty acid esters alone may increase antiviral activity, what is not known and could not have been predicted is the combination of long chain alcohols, salts of fatty acids and mixed esters would dramatically increase antiviral activity. Upon reviewing United States Patent Application Serial No. 09/899,432, based on the totality of my skill and experience, I am surprised and would not have expected the significant increase in antiviral activity of the combination of long chain alcohols, salts

of fatty acids and mixed esters as disclosed in United States Patent Application Serial No. 09/809,432.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the subject patent application or any patent issued thereon.

I further declare that I have received no special compensation or consideration for making this affidavit, nor have I been in any way told, either directly or by implication or inference, by anyone that my employment by International Flora Technologies, Inc., or my professional advancement or other matters of personal or professional interest to me depend in any way on whether or not I make this affidavit or the content thereof. I further declare that I make this affidavit of my own free will and choice without any duress or influence of any kind, believing fully in the truth of the statements made by myself herein.



David Ashley

I, Carol Hynes, a Notary Public in and for the County and State aforesaid, do hereby certify that David Ashley, whose name is subscribed to the foregoing instrument, appeared before me this day in person and acknowledge that he signed, sealed and delivered the said instrument as his free and voluntary act and deed for the uses and purposes therein set forth.

Given under my hand and Notary Seal this 19th day of April, 2006.

My commission expires on Nov. 29, 2007

SEAL

